IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAXTER HEALTHCARE CORPORATION, BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE S.A., Plaintiffs, v. HQ SPECIALTY PHARMA CORPORATION, Defendant.	HONORABLE JEROME B. SIMANDLE Civil Action No. 13-6228 (JBS/KMW) **OPINION**

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SIMANDLE, Chief Judge:

I. INTRODUCTION

In this infringement litigation under the Hatch-Waxman Act, 35 U.S.C. §§ 271, 282, Plaintiffs Baxter Healthcare Corporation, Baxter International Inc., and Baxter Healthcare S.A. (collectively, "Baxter") allege that Defendant HQ Specialty Pharma Corporation's (hereinafter, "HQ") proposed generic esmolol hydrochloride product infringes the composition and method of manufacture patents for Baxter's esmolol hydrochloride product, U.S. Patent Nos. 6,310,094 (hereinafter, "'094 Patent") and 6,528,540 (hereinafter, "'540 Patent" and collectively, the "patents-in-suit" or "Patents").[1]

Taken together, Baxter's Patents teach a stable, ready-to-use parenteral solution containing esmolol hydrochloride, a buffering agent, an osmotic-adjusting agent, and a method of manufacture, in a premixed and injectable form that Baxter markets under the trade name BREVIBLOC®. HQ's proposed competing generic product, by contrast, consists of esmolol hydrochloride, a buffering agent, a combination of ethanol and propylene glycol, and a pH adjuster.

[1] All claims require an "osmotic-adjusting agent," and so the Court will, in line with the parties' briefing, largely refer to the Patents interchangeably.

The parties now cross move for summary judgment on the issue of infringement [see Docket Items 120 & 121],[2] but agree that the disposition of this infringement litigation turns, in its entirety, upon whether HQ's generic esmolol product includes an "osmotic-adjusting agent," as defined in the patents-in-suit.[3] Stated differently, the Court must determine whether the combination of propylene glycol and ethanol in HQ's proposed esmolol product amounts to an "osmotic-adjusting agent," as disclosed in Baxter's Patents and construed by this Court.

The parties, however, assert diametrically opposed positions on the resolution of these issues. Baxter, on the one hand, takes the position that "osmotic-adjusting agent" means a component that adjusts the osmotic pressure of the composition, and asserts that it is scientifically indisputable that the inclusion of propylene glycol and ethanol in HQ's product adjusts the osmotic pressure of the composition. (See, e.g., Baxter's Br. at 1-2, 10-18.) As a result, Baxter claims that the undisputed record demonstrates its entitlement to a summary finding that HQ's proposed esmolol product includes an "osmotic-

[2] In addition, HQ moves to strike Baxter's motion for summary judgment on the grounds discussed below. [See Docket Item 132.]
[3] Indeed, on March 27, 2014, the Court, through the formerly-assigned District Judge, entered a Consent Order memorializing the parties' agreement that HQ's proposed esmolol products satisfy all limitations of the asserted claims of the patents-in-suit, other than the "osmotic-adjusting agent." [Docket Item 38.]

adjusting agent" and therefore infringes the patents-in-suit. HQ, by contrast, argues that Baxter's prior admissions and the Patents themselves amply demonstrate that "osmotic-adjusting agent" means a component that adjusts the tonicity of the solution (rather than its osmotic pressure),[4] and asserts that the combination of propylene glycol and ethanol in HQ's product plainly fails to perform such function. (See, e.g., HQ's Br. at 1-2, 6-18.) HQ therefore submits that HQ's proposed esmolol product lacks the "osmotic-adjusting agent" disclosed by the patents-in-suit, thereby demonstrating its entitlement to a summary finding of non-infringement. (See generally HQ's Reply.)

In resolving these issues, the Court must address two related inquiries. First, the Court must construe the term "osmotic-adjusting agent" based upon well-established claims construction principles. Second, the Court must determine whether the undisputed evidence demonstrates that HQ's allegedly infringing product contains the properly construed "osmotic-adjusting agent."

[4] At earlier phases of the litigation, HQ proffered a more expansive definition of "osmotic-adjusting agent." (See generally HQ's Opening Claim Constr. Br.) Nevertheless, the pending submissions make plain that HQ now puts forth only a narrow portion of its original construction, and the Court has analyzed HQ's position accordingly. (Compare id., with HQ's Br. & Reply.)

For the reasons that follow, Baxter's motion for summary judgment will be denied, HQ's motion to strike Baxter's motion for summary judgment will be denied, and HQ's motion for summary judgment will be granted on the issue of claim construction, but denied on the issue of non-infringement.[5]

II. BACKGROUND[6]

A. Factual and Procedural Background

1. The Parties

Baxter, a global healthcare and pharmaceutical conglomerate, develops, manufactures, and sells products for an array of medical conditions, including BREVIBLOC®, an esmolol hydrochloride formulation for the treatment of acute cardiac disorders. (See Second Am. Compl. at ¶ 4; see also Baxter's SMF at ¶¶ 1-3.)

HQ identifies itself as a specialty pharmaceutical company that develops proprietary treatments for the hospital and specialty markets (see Second Am. Compl. at ¶ 5), and seeks approval to market a generic esmolol product in order to compete with BREVIBLOC®. (See HQ's SMF at ¶ 3.)

[5] The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338(a).

[6] The Court derives the undisputed facts stated herein from the parties' various statements of material facts, affidavits, and exhibits, unless otherwise indicated.

2. Background to the Claimed Invention: Esmolol Hydrochloride

Esmolol hydrochloride constitutes one type of "beta-blocker," a class of drugs that block the "beta" receptor of heart muscles, arteries, and certain other tissue. ('094 Patent at 1:13-23.) With this large class of drugs, however, esmolol proves unique because of its "short-acting" nature, making it "often desirable in the critical care setting to quickly reduce heart work or improve rhythmicity during a cardiac crisis." (Id.)

Prior art esmolol formulations, however, suffered from a number of deficiencies, namely, "extreme susceptibility to hydrolytic degradation" and "severe degradation upon autoclaving."[7] ('540 Patent at 1:30-40.) In other words, the prior art esmolol compositions readily broke down in the presence of water, and proved incapable of effective terminal sterilization (requiring that the formulations instead be sterilized aseptically in a "clean" environment). ('094 Patent at 1:40-49; '540 Patent at 2:1-41.)

[7] Autoclaving refers to a form of sterilization that subjects a product in its final packaging to a combination of heat and steam for a period of time sufficient to kill any microorganisms. (See Ex. 4 to Evans Dec. at ¶ 27.)

3. Baxter's Innovative Esmolol Hydrochloride Product, BREVIBLOC®

Through the patents-in-suit, Baxter claims to have solved these problems, and developed a ready-to-use aqueous esmolol formulation capable of sterilization by autoclaving. ('094 Patent at 2:1-14; '540 Patent at 2:1-14.) Indeed, in contrast to the prior art, the claimed formulations prove "stable against hydrolytic degradation and other adverse chemical reactions," and possess "a pharmaceutically-acceptable shelf-life." ('094 Patent at 2:3-5.)

The patents-in-suit include both composition and method of manufacture claims. Claim 1 of the '094 Patent, for example, discloses the following:

> 1. An injectable, aqueous pharmaceutical composition for the treatment of cardiac conditions, having a pH between 3.5 and 6.5 and comprising:
>
> a. 0.1-100 mg/ml methyl-3-[4-(2-hydroxy-3-isopropylamino) propoxy] phenylpropionate hydrochloride (**esmolol hydrochloride**),
>
> b. 0.1-5.0 mg/ml **buffering agent**, and
>
> c. 1-100 mg/ml **osmotic-adjusting agent**.

(Baxter's SMF at ¶ 4 (citation omitted) (emphases added).) Claim 13 of the '540 Patent similarly teaches:

> 13. A method for preparing an aqueous, sterile pharmaceutical composition suitable for parenteral administration for the treatment of cardiac conditions, comprising forming an aqueous composition having a pH between 3.5 and 6.5 comprising 0.1-500 mg/ml methyl-3-[4-(2-hydroxy-3-isopropylamino) propoxy]phenylpropionate hydrochloride (**esmolol hydrochloride**), 0.01-2 M **buffering agent**, and 1-500 mg/ml **osmotic-adjusting agent** in a sealed container

> and autoclaving for a period of time sufficient to render the composition sterile.

(Baxter's SMF at ¶ 5 (citation omitted) (emphases added).)

Following the issuance of these Patents, the United States Food and Drug Administration (hereinafter, the "FDA"), approved Baxter's New Drug Application (hereinafter, "NDA") No. 19-386 for BREVIBLOC® Premixed Injection, a short-acting esmolol hydrochloride solution indicated for the rapid control of an abnormal heart rhythm in perioperative, postoperative, or other emergent circumstances. (See Baxter's SMF at ¶ 3; see also Second Am. Compl. at ¶ 33.)

In connection with BREVIBLOC's® listing in the Orange Book, the FDA's book of drug products approved under the Food, Drug, and Cosmetic Act (hereinafter, the "Orange Book"), 21 U.S.C. § 355(j), Baxter identifies the '094 Patent, the '540 Patent, and BREVIBLOC's® two dosage forms, 10 mg/mL and 20 mg/mL. (Baxter's SMF at ¶ 3; see also Second Am. Compl. at ¶¶ 28-29; Ex. 3 to Evans Dec.)

4. HQ's Proposed Esmolol Hydrochloride Premixed Injection Products

In June 2013, HQ requested FDA approval to sell generic esmolol products in 10 mg/mL and 20 mg/mL dosage forms, prior to the expiration of the patents-in-suit. (See Baxter's SMF at ¶ 6; HQ's SMF at ¶ 3.) Like BREVIBLOC®, HQ's NDA No. 205-703 lists esmolol hydrochloride as the active ingredient, and identifies the remaining ingredients and their functions as follows:

Table 1: Components of Esmolol HCl Premixed Injections

Name of Ingredients	Grade	Function
Esmolol Hydrochloride	USP	Active Ingredient
Sodium Acetate Trihydrate	USP	Buffering Agent
Glacial Acetic Acid	USP	Buffering Agent
Ethanol	USP	Stabilizer
Propylene Glycol	USP	Stabilizer
Sodium Hydroxide	USP	pH Adjuster
WFI	USP	Vehicle

(Baxter's SMF at ¶ 8; HQ's RSMF at ¶ 8.)

5. Litigation in this District

As a result of HQ's NDA filing, Baxter filed a Second Amended Complaint in this District on January 16, 2015,[8] alleging that HQ's submissions of an NDA application prior to the expiration of the patents-in-suit constitutes infringement.[9]

[8] Baxter filed its initial Complaint on October 18, 2013 [see Docket Item 1], followed by an Amended Complaint on June 20, 2014. [See Docket Item 52].

[9] In addition, Baxter asserts a number of stated law tort and trade secret-based claims, arising from the fact that one of the named inventors of the patents-in-suit, George Owoo, purportedly

(See generally Second Am. Compl. at ¶¶ 65-74.) Following an unusual pretrial process before the previously-assigned (and now retired) District Judge Faith S. Hochberg,[10] the pending motions followed.

III. STANDARD OF REVIEW

Because the construction of "osmotic-adjusting agent" has been presented in the context of competing motions for summary judgment on the issue of infringement, the Court first addresses the general summary judgment standard, prior to turning to the more-specific standards applicable to claim construction and patent infringement.

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assisted HQ—"unbeknownst to Baxter"—in developing its generic product by disclosing "highly valuable and competitively sensitive confidential information and trade secrets" in direct contravention of his contractual nondisclosure and non-compete obligations. (Second Am. Compl. at ¶¶ 51-60, 75-139.)

[10] The parties filed their opening Markman submissions on September 19, 2014 [see Docket Items 65, 66, 81-2], followed shortly thereafter by HQ's first motion for summary judgment of non-infringement. [See Docket Item 69.] On October 9, 2014, the Judge Hochberg administratively terminated HQ's motion, because the motion depended upon the Court's construction of "osmotic-adjusting agent." [Docket Item 79.] Following the parties' responsive Markman submissions [see Docket Items 82 & 83], Judge Hochberg convened a Markman hearing on January 8, 2015 [see Docket Item 101], at which time she determined that the issue of claim construction should be decided in the context of summary judgment motions on the issue of infringement. As a result, the previously-assigned District and Magistrate Judges entered Scheduling Orders on January 28, 2015 and February 20, 2015, which required the parties' respective summary judgment motions to be fully briefed by no later May 15, 2015. [See Docket Item 102 & 123.] This action was reallocated and reassigned to the undersigned on March 9, 2015. [See Docket Item 127.] The briefing on the present cross-motions was not completed until June, 2015.

A. Summary Judgment, Generally

Federal Rule of Civil Procedure 56(a) generally provides that the "court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact" such that the movant is "entitled to judgment as a matter of law." FED. R. CIV. P. 56(a).

In evaluating a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-moving party, and must provide that party the benefit of all reasonable inferences. See Scott v. Harris, 550 U.S. 372, 378 (2007); Halsey v. Pfeiffer, 750 F.3d 273, 287 (3d Cir. 2014).

B. Claim Construction Standard[11]

Claim construction focuses upon the intrinsic evidence, "including the claims themselves, the specification, and the prosecution history of the patent."[12] Sunovion Pharm., Inc. v.

[11] The construction of claim terms constitutes a question of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996), and the Court need not follow the parties' proposed constructions. See Marine Polymer Techs., Inc. v. HemCon, Inc., 672 F.3d 1350, 1359 n.4 (Fed. Cir. 2012) (en banc).

[12] If, however, the intrinsic evidence fails to disclose the meaning of a term, the Court may examine extrinsic evidence to determine the meaning of particular terminology to those of skill in the art of the invention. Phillips, 415 F.3d at 1318. The Court of Appeals for the Federal Circuit, however, cautions against "heavy reliance" upon extrinsic sources divorced from the intrinsic evidence because it "risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract," and out of the context of the specification." Id. at 1321.

Teva Pharm. USA, Inc., 731 F.3d 1271, 1276 (Fed. Cir. 2013) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1315–17 (Fed. Cir. 2005) (en banc); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Claim terms must, however, ordinarily be "given their plain and ordinary meanings to one of skill in the art" at the time of the invention "when read in the context of the specification and prosecution history." Golden Bridge Tech., Inc. v. Apple Inc., 758 F.3d 1362, 1365 (Fed. Cir. 2014) (citing Phillips, 415 F.3d at 1315–17). Nevertheless, the Court of Appeals for the Federal Circuit has routinely stated that "'[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.'" Shire Dev., LLC v. Watson Pharms., Inc., 746 F.3d 1326, 1330 (Fed. Cir. 2014) (quoting Phillips, 415 F.3d at 1316).

C. Patent Infringement Standard

A claim for patent infringement lies whenever an entity "without authority makes, uses or sells any patented invention, within the United States" during the life of the patent." 35 U.S.C. § 271(a). The patent infringement analysis involves two steps: first, the Court must construe the asserted claim terms.[13]

[13] For that reason alone, the Court rejects HQ's assertion that the issue of infringement can be resolved on summary judgment without resorting to claim construction, based upon Baxter's alleged "admissions" that propylene glycol and ethanol do not

See, e.g., Purdue Pharma L.P. v. Boehringer Ingelheim, GMBH, 237 F.3d 1359, 1363 (Fed. Cir. 2001). Claim construction constitutes, as stated above, a question of law. See Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1454 (Fed. Cir. 1998). Second, the claims, as construed, must be compared with the accused infringing product. See Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001) (citation omitted). This second stage of the analysis amounts to a question of fact. See Kustom Signals, Inc. v. Applied Concepts, Inc., 264 F.3d 1326, 1332 (Fed. Cir. 2001) (Patent infringement, "whether literal or under the doctrine of equivalents, is a question of fact.").

In order to prevail, the patentee must demonstrate by a preponderance of the evidence that the accused device infringes one or more claims of the patent either literally or under the doctrine of equivalents. Id.; see also Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 758 (Fed. Cir. 1984) (citation omitted). In patent infringement suits, summary judgment may be

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amount to osmotic-adjusting agents in the esmolol formulations at issue in this case. See Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298 (Fed. Cir. 2003) (finding that "the district court erred as a matter of law" in granting summary judgment of non-infringement without first construing the disputed claim term, because meaningful appellate review requires that the appellate court "know what meaning and scope the district court gave to the asserted claims"). Rather, the Court regards Baxter's alleged admissions as appropriate for consideration as evidence of specification disavowal, but not as a substitute for claim construction.

granted only if the undisputed record evidence demonstrates that only one conclusion regarding infringement could be reached by a reasonable jury. See Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1376 (Fed. Cir. 2005); TechSearch, LLC v. Intel Corp., 286 F.3d 1360, 1369 (Fed. Cir. 2002); Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1323 (Fed. Cir. 2001). In other words, summary judgment may be granted only if, after viewing the facts in the light most favorable to the non-movant, the Court finds no genuine issue as to whether the construed claims of Baxter's Patents cover HQ's accused product. See Pitney Bowes, Inc. v. Hewlett–Packard Co., 182 F.3d 1298, 1304 (Fed. Cir. 1999).

IV. DISCUSSION

A. HQ's Motion to Strike Baxter's Motion for Summary Judgment

The Court addresses, at the outset, HQ's cross-motion to strike Baxter's motion for summary judgment, on the grounds that Baxter's argument in support of summary judgment rests upon a newly minted, and previously undisclosed, construction of the term "osmotic-adjusting agent." (See HQ's Opp'n at 26-29.)

HQ specifically asserts that Baxter has, throughout this litigation, long maintained the position that "osmotic-adjusting agent" means a discrete component "that adjusts the osmotic pressure of the composition." (Id. at 28 (emphasis omitted).)

In connection with the present briefing, however, Baxter purportedly argues, for the first time, that an "osmotic-adjusting agent" means a component that stabilizes the esmolol formulation for autoclaving. (Id.) HQ therefore argues that this "belated construction" amounts to "argument by ambush," because Baxter "manipulate[d] the discovery, Markman, and dispositive motion process" by asserting, at the summary judgment stage, "a new claim construction" without providing HQ the opportunity "to vet" the construction. (HQ's Opp'n at 28-29.)

The Court, however, need not belabor HQ's position, because Baxter's submissions make plain that it has, from the very outset of the claim construction process, proposed that "osmotic-adjusting agent" be defined as "a component added to the composition that adjusts its osmotic pressure." (See, e.g., Ex. P to West Dec. (setting forth Baxter's proposed construction); Baxter's Opening Claim Constr. Br. at 1, 13-20 (arguing for the same construction); Baxter's Responsive Claim Constr. Br. at 4 (same).) And so, Baxter unsurprisingly proposes the same construction in its pending motion for summary judgment. (See Baxter's Br. at 1 (arguing that the term "osmotic-adjusting agent" should be construed as "a component that adjusts the osmotic pressure of the composition").) Indeed, Baxter's citations to the patents' teachings as to the

nature of the claimed inventions (an aqueous esmolol formulation with enhanced stability to autoclaving) provided only the contextual background for Baxter's challenges to HQ's counter-proposed construction, not any last-minute change to its own construction.

For all of these reasons, HQ's motion to strike Baxter's motion for summary judgment is frivolous and it will be denied. The Court will address both motions on their merits.

B. "Osmotic-Adjusting Agent" means "an agent to adjust the tonicity of the solution"

The Court notes, at the outset, that HQ does not genuinely dispute that Baxter's proposed construction embodies the ordinary meaning of the term "osmotic-adjusting agent." (See, e.g., HQ's Am. Opening Claim Constr. Br. at 1-2, 8, 12; HQ's Reply at 4.) Rather, HQ focuses upon the lack of "ambiguity in the intrinsic record regarding the [special] meaning of 'osmotic-adjusting agent'" set forth in the patents-in-suit (HQ's reply at 8), and argues that the patentees restrictively re-defined "osmotic-adjusting agent" to encompass only agents that "'adjust the tonicity of the solution.'" (See, e.g., Berkland Opening Dec. at ¶ 21 ("'osmotic-adjusting agents' as defined by the patents-in-suit are expressly limited to those that can be used to adjust tonicity of the solution"), and ¶ 45 ("the '540 and '094 patents restrictively define the 'osmotic-

adjusting agent' to be only agents that 'adjust the tonicity of the solution'") (emphases added).) In other words, HQ principally argues that, for purposes of the patents-in-suit, Baxter adopted a special definition of "osmotic-adjusting agent" apart from its ordinary meaning.

Words of a claim must, ordinarily, be given their ordinary and customary meaning when viewed through the lens of the specification and prosecution history. A patentee may, however, deviate from the plain and ordinary meaning, when it "sets out a definition and acts as his own lexicographer," or "when the patentee disavows the full scope of a claim term either in the specification or during prosecution." Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citation omitted). While "no magic words" trigger either exception, Hill-Rom Servs. v. Stryker Corp., 755 F.3d 1367, 1373 (Fed. Cir. 2014), the standards for finding lexicography and disavowal prove "'exacting.'" Pacing Techs., LLC v. Garmin Int'l, Inc., 778 F.3d 1021, 1024 (Fed. Cir. 2015) (quoting GE Lighting Solutions, LLC v. AgiLight, Inc., Inc., 750 F.3d 1304, 1309 (Fed. Cir. 2014)).

Specifically, to act as a lexicographer, a patentee must "clearly set forth a definition of the disputed claim term" and "clearly express an intent to define the term." Thorner, 669 F.3d at 1365 (quoting CCS Fitness, Inc. v. Brunswick Corp., 288

F.3d 1359, 1366 (Fed. Cir. 2002)). In other words, the patentee must do more than simply disclose a single embodiment. See Thorner, 669 F.3d at 1366. Rather, the patentee must "'clearly express,'" through the written description or elsewhere, the intention to define the term apart from its plain and ordinary meaning. See id. (quoting Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1381 (Fed. Cir. 2008); citing Kara Tech. Inc. v. Stamps.com, 582 F.3d 1341, 1347–48 (Fed. Cir. 2009)); see also C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (noting that the "inventor's written description of the invention" may prove "relevant and controlling insofar as it provides clear lexicography").

Similarly, disavowal requires that "'the specification [or prosecution history] make[] clear that the invention does not include a particular feature.'" Pacing, 778 F.3d at 1024 (quoting SciMed Life, 242 F.3d at 1341). And so, the Court of Appeals for the Federal Circuit has, for example, found disavowal based upon limiting statements "such as 'the present invention includes...' or 'the present invention is...' or 'all embodiments of the present invention are....'" Id. (citations omitted). Or, where a specification deemed a particular step "'require[d]'" or characterized a specific feature as "'an important feature of the present invention.'" Id. (citations omitted). Indeed, under such circumstances, the patentee

"alerts the reader that 'th[e] description limits the scope of the invention," id. (citation omitted), "'even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.'" Thorner, 669 F.3d at 1366 (quoting SciMed Life, 242 F.3d at 1341). In the absence of a sufficiently clear disavowal, however, the patentee should receive the benefit of "the full scope of its claim language." Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004).

In applying this standard to the patents-in-suit, the Court inescapably concludes that the patentees disavowed or disclaimed any meaning of "osmotic-adjusting agent" beyond an "agent to adjust [the] tonicity of the [claimed] invention."

Critically, the relevant provisions of the patents-in-suit prove remarkably brief, but unequivocal. Indeed, the Claims themselves provide almost no information from which to divine the meaning of "osmotic-adjusting agent," aside from defining the osmotic-adjusting agent in the claimed solution as comprising "at least one of sodium chloride, dextrose, sodium bicarbonate, calcium chloride, potassium chloride, sodium lactate, Ringer's solution and lactated Ringer's solution." ('094 Patent at 5:8-6:22; '540 Patent at 5:60-8:11.) Nevertheless, **at the outset** in sections entitled the "Detailed

Description of the Invention," the patents-in-suit explicitly teach that the claimed invention contains an "osmotic-adjusting agent to adjust the tonicity of the solution." ('094 Patent at 1:64-65; '540 Patent at 2:5-6.)

Indeed, the '094 Patent states that the "present invention provides a stable, ready-to-use parenteral solution containing esmolol hydrochloride and a pharmaceutically acceptable buffering agent and an osmotic adjusting agent **to adjust the tonicity of the solution**." ('094 Patent at 1:62-65 (emphasis added).) The '540 Patent similarly discloses that the "present invention provides a stable, ready-to-use parenteral composition containing esmolol hydrochloride and a pharmaceutically acceptable buffering agent and an osmotic adjusting agent **to adjust the tonicity of the solution**." ('540 Patent at 2:62-65 (emphasis added).) The Court can scarcely imagine a more concise and unequivocal expression concerning the scope and construction of the term "osmotic-adjusting agent."[14] Indeed,

[14] The Court rejects Baxter's position that a "single statement in the patent specifications" proves unreliable for purposes of claim construction. (See Baxter's Reply at 6.) Indeed, "brevity in a patent disclosure should be applauded, not impugned," and a "disclosed embodiment is a disclosed embodiment, no matter the volume of ink required to adequately describe it." Advanced Fiber Techs. Trust v. J&L Fiber Servs., 674 F.3d 1365, 1375 (Fed. Cir. 2012). For that reason, a "'one-sentence mention'" may prove equally dispositive to a far lengthier disclosure, and does so in this instance. See id. ("the fact that an embodiment is disclosed in a single sentence is not a license to ignore that disclosure"); see also Falkner

the conciseness of the disclosure provides "strong evidence" that the term "osmotic-adjusting agent" should be read to encompass no more than that disclosed in the specification, particularly because the patents-in-suit make no mention of osmotic pressure (i.e., Baxter's proposed construction).[15] See SciMed, 242 F.3d at 1343.

Even more, the language of the specification—the "present invention" together with an expressly limited definition of "osmotic-adjusting agent"—squarely matches the language routinely deemed indicative of disavowal by the Federal Circuit, see, e.g., Pacing, 778 F.3d at 1024-36 (finding that the specification's use of the "'present invention'" imposed a "clear[] and unmistakabl[e]" limitation upon the claimed invention); X2Y Attenuators, LLC v. ITC, 757 F.3d 1358, 1362 (Fed. Cir. 2014) (finding the patentee's use of the phrase

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v. Inglis, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006) ("No length requirement exists for a disclosure to adequately describe an invention.")

[15] The terms "osmotic pressure" and "tonicity" embody markedly different concepts. Indeed, in their joint technology tutorial, the parties define "osmotic pressure" as a quantitative measurement of the amount of pressure necessary to stop osmosis (i.e., to stop the net flow of water across the membrane). (See Ex. 14 to Evans Dec. at 10 (reproducing the Joint Technology Tutorial submitted by the parties in connection with the Markman hearing); see also Bannister Claim Constr. Dec. at ¶ 53 (defining "osmotic pressure").) "Tonicity," by contrast, constitutes a qualitative term that refers to the tendency of a solution to alter the specified cell's tone, or natural shape, when the solution comes into contact with that cell. (Ex. 14 to Evans Dec. at 16-17; see also Bannister CC Dec. at ¶¶ 60-61 (defining the term "tonicity").)

"'essential element'" demonstrated "a clear and unmistakable disavowal of claim scope"), and Baxter has not pointed to any contrary portions of the intrinsic record. See Absolute Software, Inc. v. Stealth Signal, Inc., 659 F.3d 1121, 1136 (Fed. Cir. 2011) (citations omitted) ("a patentee's consistent reference to a certain limitation or a preferred embodiment as 'this invention' or the 'present invention' can serve to limit the scope of the entire invention, particularly where no other intrinsic evidence suggests otherwise"). Nor has Baxter, or its expert Steve J. Bannister, Ph. D, provided a sufficiently strongly basis to read away the specifications' otherwise clear disclosure.[16] Rather, Baxter attempts to pivot the focus of the analysis from the actual words of the patents-in-suit to the overall novel aspects of the claimed invention, namely, its enhanced stability to autoclaving. Nevertheless, novelty and claim construction require distinct inquiries, see Markman, 517 U.S. at 384-88 (distinguishing the novelty inquiry from claim

[16] Indeed, Dr. Bannister's opening claim construction declaration did not even address the relevant portion of specification of the patents-in-suit (see Bannister Claim Constr. Dec. at ¶¶ 71-93), and his rebuttal declaration merely rejects the critical portion of the specification out of hand as a "lone statement." (Bannister Rebuttal Claim Constr. Dec. at ¶¶ 23-35.) Dr. Bannister further states his belief that "osmotic pressure/osmoticity" and "cell tone/tonicity" amount to mismatched, or distinct, concepts, but again fails to account for the fact that the Patents themselves make an explicit connection between an "osmotic-adjusting agent" and an agent that adjusts tonicity. ('094 Patent at 1:64-65; '540 Patent at 2:5-6.)

construction), and the patents-in-suit make no direct connection between osmotic-adjusting agents and the stability of the claimed invention to autoclaving. (See generally ('094 Patent; '540 Patent.)

For these reasons, the Court finds that the phrase "present invention..." clearly and unmistakably limits the term "osmotic-adjusting agent" to an agent that adjusts the tonicity of the claimed solution.[17]

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[17] Nor do the cases relied upon Baxter compel any different conclusion. Indeed, in Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331-32 (Fed. Cir. 2004), the Federal Circuit considered whether the following statement within the specification limited the claimed "wireless, remote-controlled, portable search light" to a device that rotated through 360°:

> the present invention includes a lamp unit mounted in a housing which has a motor-driven vertical drive mechanism for tilting the lamp unit in a vertical direction and a motor-driven horizontal drive mechanism for rotating the lamp unit in a horizontal direction through at least 360°.

Id. at 1331 (citation omitted). In finding this language insufficient to demonstrate disavowal, the Golight court emphasized that other portions of the written description described distinct features of the invented search light. See id. Therefore, the Court could not find the description of one such feature sufficiently clear for purposes of disavowal. See id. Here, by contrast, the "osmotic-adjusting agent" constitutes one of the three critical components of the patents-in-suit, which the patents clearly and **only** defined in the written description. (See, e.g., '094 Patent at 1:64-65; '540 Patent at 2:5-6.) The remaining cases relied upon by Baxter prove equally unconvincing, and none concern specification language with clarity of that contained within the patents-in-suit. See, e.g., Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 908-09 (Fed. Cir. 2004) (refusing to read references in the "Summary of the Invention" section describing the "present invention" as including a "pressure jacket" to require the use

Moreover, even in the absence of this clear disavowal of claim scope, the Court finds creditable HQ's position that Baxter has, on at least one occasion, admitted that the term "osmotic-adjusting agent" means—for purposes of the technological field of the patents-in-suit—an agent that adjusts tonicity (and not one that affects osmotic pressure). Indeed, in prosecuting the European equivalent of the '094 Patent, E.U. Patent No. EP 1 368 019 B1 (hereinafter, "EP 1 Patent"),[18] Dr.

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of pressure jackets, because no language suggested that a "pressure jacket" constituted "an essential component of the invention"); Absolute Software, 659 F.3d at 1137 (finding a description of the "present invention" insufficient to give rise to disavowal, because "other portions of the intrinsic evidence" proved inconsistent and did "not support applying the limitation to the entire patent")

[18] Baxter argues that its proceedings before the European Patent Office (hereinafter, the "EPO") have no relevance to the pending motion, because the disputed claims of the EP 1 Patent "were very different in scope than the asserted claims of the '094 and '540 Patents." (Baxter's Opp'n at 10.) In support of this assertion, Baxter points to the fact that each of the allowed EP 1 claims expressly limited "osmotic-adjusting agents" to a specified list (selected from at least one of sodium chloride, dextrose, sodium bicarbonate, calcium chloride, potassium chloride, sodium lactate, Ringer's solution and lactated Ringer's solution), while the patents-in-suit broadly ensnare the use of any osmotic-adjusting agent suitable for use in injectable formulations (rather than only those on the specified list of eight osmotic-adjusting agents). (Id. at 10-11.) Nevertheless, even a cursory comparison of the disclosures of the EP 1 Patent with the patents-in-suit reveals that the patents are substantially, if not entirely, identical. (Compare '094 Patent and '540 Patent, with Exs. C & E to West Dec. (reproducing the essentially identical disclosures of the EP 1 patent).) Indeed, Baxter concedes that EP 1 constitutes the "European counterpart" of the patents-in-suit (Baxter's Opp'n at 10), and the "Detailed Description" of the EP 1 Patent identically discloses that the claimed invention "provides a

Mahesh Chaubal, a Director of Product Development in Global R&D within the Medication Delivery division of Baxter, submitted a declaration on esmolol formulations, explaining that EP 1, like the patents-in-suit, "specifies a composition that comprises of Esmolol hydrochloride (active ingredient), a buffering agent, and an osmotic-adjusting agent." (Ex. J to West Dec. at ¶ 4.) Dr. Chaubal then critically stated that persons familiar with the relevant state-of-the-art use the term "'tonicity agent' ... synonymously with 'osmotic-adjusting agent.'" (Id.)

This unequivocal representation by Baxter's own agent squarely reflects that those of ordinary skill in the precise art implicated in the pending action use the term "osmotic-adjusting agent" to mean tonicity agent. (Id.) In other words, Baxter's own scientist broadly stated that "osmotic-adjusting agent" should, for purposes of the esmolol formulations at issue in this litigation, be understood to mean an agent that adjusts tonicity, and not one that adjusts osmotic pressure (as Baxter now proposes). Even more importantly, Dr. Chaubal's statement proves entirely consistent with the disclosures of the patents-

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stable, parenteral composition containing esmolol hydrochloride and a pharmaceutically acceptable buffering agent and an osmotic adjusting agent to adjust the tonicity of the solution." (Ex. E to West Dec. at 2.) Therefore, although the varied claims limitations between the EP 1 and the patents-in-suit might impact an infringement analysis, these slight variations do not alter the overall relevance of the EP 1 for purposes of construing the substantially similar claims of the patents-in-suit.

in-suit, both of which describe "osmotic-adjusting agent" as a component to adjust tonicity (and not one to adjust osmotic pressure).

The Court of Appeals for the Federal Circuit "cautions against indiscriminate reliance on the prosecution of corresponding foreign applications in the claim construction analysis," AIA Eng'g Ltd. v. Magotteaux Int'l S/A, 657 F.3d 1264, 1279 (Fed. Cir. 2011), particularly if the statements made during the foreign prosecution arose in response to unique aspects of foreign patent law. See Pfizer, Inc. v. Ranbaxy Labs. Ltd., 457 F.3d 1284, 1290 (Fed. Cir. 2006) ("[S]tatements made during prosecution of foreign counterparts to the '893 patent are irrelevant to claim construction because they were made in response to patentability requirements unique to Danish and European law."). Nevertheless, the Federal Circuit has routinely approved reliance upon statements in foreign prosecutions where they constituted "blatant admissions" directed at the relevant art, see Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1374 (Fed. Cir. 2005) (considering the patentee's arguments before the EPO and concluding that a "blatant admission by this same defendant before the EPO clearly support[ed]" the court's construction), and where the statements proved otherwise "consistent with the claims and the invention described in the specification" at

issue. Apple, Inc. v. Motorola, Inc., 757 F.3d. 1286, 1313 (Fed. Cir. 2014) (citing AIA, 657 F.3d at 1279); see also Tanabe Seiyaku Co. v. ITC, 109 F.3d 726, 733 (Fed. Cir. 1997) (finding that the ITC correctly considered statements made by the patentee before the EPO in prosecuting foreign counterparts to the patent-in-suit when determining infringement); Starhome GmbH v. AT&T Mobility LLC, 743 F.3d 849, 858 (Fed. Cir. 2014) (considering the patentee's statements before the EPO as "yet another indication" that supported the court's construction).

Application of these principles to this action provides ample support for holding Baxter to its statements during the European prosecution. Critically, Dr. Chaubal's statements did not, as described above, relate to the more limited claims of the EP 1, nor did his statements arise in response to patentability requirements unique to European law. Indeed, Dr. Chaubal's remark that "'tonicity agent'" means "'osmotic-adjusting agent'" could not be more sweeping and clear. (Ex. J to West Dec. at ¶ 4.) Moreover, the EP 1, an indisputably related patent to the patents-in-suit, has an identical specification in relevant part, and Dr. Chaubal's explanation proves entirely consistent with the invention described by the specification of the patents-in-suit. Therefore, the Court finds that Baxter's statements to the EPO lend further support

for the construction supported by the specification.[19] See Apple Inc., 757 F.3d at 1313 (holding a party to a "clear[]" statement made to the Japanese patent office); Gillette, 405 F.3d at 1374 (holding a party to "blatant admission" to the EPO); Starhome GmbH, 743 F.3d at 858 (same).

For all of these reasons, the Court construes "osmotic-adjusting agent" in accordance with the disclosures of the patents-in-suit and Baxter's prior statements as "**an agent to adjust the tonicity of the solution**."

C. Factual Disputes Preclude the Entry of Summary Judgment Favorably to Either Party

In light of the Court's construction of an "osmotic-adjusting agent," the remaining issue in connection with the parties' competing summary judgment motions collapses to whether a genuine issue of fact exists concerning whether propylene

[19] In light of the strength of consistency of Baxter's statement to the EPO with the specifications of the patents-in-suit, the Court need not reach the two additional references relied upon by HQ, which, in any event, prove less persuasive. (See, e.g., HQ's Br. at 7-11; HQ's Opp'n at 6-9, 15-17; HQ's Reply at 7-12; HQ's Surreply at 13-15.) Indeed, the Patent Examiner's Notice of Allowance for the '094 Patent states that "the prior art fails to teach or suggest the inclusion of an osmotic agent" and makes no mention of tonicity or osmotic pressure. (Ex. H to West Dec.) HQ's argument that the Notice amounts to anything more therefore rests upon unsupported inference and speculation, and provides no instructive information for purposes of the claim construction here. (See id.) Similarly, the Court cannot find Baxter's unrelated Patent Application No. 293814 A1 relevant for purposes of construing the patents-in-suit. (See Ex. G to West Dec.) See also Apple, Inc., 757 F.3d at 1312 (noting that "unrelated applications" prove irrelevant to claim construction).

glycol and ethanol act as tonicity adjusters for purposes of HQ's proposed esmolol product. Nevertheless, the Court need not belabor this issue, because material factual disputes pervade the records respectively developed by both parties.[20]

Baxter, for its part, principally relies upon two pieces of information in support of its position that propylene glycol and ethanol act as tonicity adjusters. (See generally Baxter's Br. at 17-18; see also Baxter's Reply at 16-22.) First, Baxter claims that HQ's expert, Dr. Cory J. Berkland, and corporate designee, Jeanne Squeglia, both testified, "consistent with the science of injectable pharmaceutical formulations," that "agents that adjust osmotic pressure also adjust tonicity." (Baxter's Reply at 20 (citing Berkland Dep. at 65:16-69:1; Squeglia Dep. at 241:17-22).) Second, Baxter points to the fact that many unrelated patents and patent applications "specifically describe propylene glycol as a tonicity-adjusting agent."[21] (Baxter's Reply at 20.) For primarily these reasons, Baxter claims that, at least "propylene glycol adjusts the tonicity of the

[20] Indeed, the parties' submissions quite frankly leave a series of unanswered questions, all of which is compounded by the fact that much of the parties' briefing focuses upon the construction of "osmotic-adjusting agent" as an agent to adjust osmotic pressure (and not solely upon the construction now adopted by the Court). For purposes of the present discussion, however, the Court need not recite every relevant factual dispute, and instead focuses upon a few examples.

[21] Baxter, however, makes no similar assertion about ethanol. (See generally Baxter's Reply.)

composition, and therefore qualifies as an 'osmotic adjusting agent.'" (Id.)

Neither of these arguments, however, proves sufficient to demonstrate Baxter's entitlement to summary judgment on the issue of infringement, nor do these assertions rely upon undisputed facts. Indeed, the infringement inquiry does not end simply because one agent may function in two capacities, namely, as both an osmotic-adjusting agent and a tonicity agent. Rather, it must be shown that the particular agent, here propylene glycol and ethanol, actually functions as a tonicity agent within the claimed invention—a claim which HQ genuinely disputes. (See HQ's RSMF at ¶¶ 19-20; see also Berkland Dec. at ¶ 59 (arguing that "propylene glycol and ethanol" act "primarily as solvents," and not to adjust tonicity).)

Even more, this Court cannot ignore, as pointed out by HQ (see HQ's Surreply at 9-14),[22] that the '540 Patent provides some genuine support for HQ's position that propylene glycol and ethanol function only to adjust tonicity in esmolol formulations. Indeed, the specification creates the impression

[22] The Court's February 20, 2015 Consent Order Regarding Summary Judgment Briefing and Procedure permitted the parties to file surreplies "limited to addressing" any responsive declarations. [Docket Item 123.] Baxter objects to HQ's Surreply on the grounds that it exceeds the limited leaved granted by the Court. [See Docket Item 165.] Nevertheless, given the complexity of the issues presented in connection with the pending motions, and the absence of any demonstrable prejudice to HQ, the Court has, in its discretion, considered the Surreply.

that prior art esmolol solutions only used ethanol and propylene glycol "to increase solubility of the esmolol," and not for the purpose of adjusting tonicity.[23] ('540 Patent at 1:44-47.) Similarly, prior art referenced by the '540 Patent and cited on the face of the '094 Patent, U.S. Patent No. 4,857,552 ("the '552 patent"), specifically states that "esmolol formulations use alcohol [i.e., ethanol] and propylene glycol to minimize the concentration of water in the formulation [by solubilizing] and, therefore, slow this degradation pathway." (Ex. 1 to West Dec.) The Court cannot weigh this competing evidence on Baxter's motion for summary judgment.

The record developed by HQ suffers from deficiencies for two related reasons. First, HQ claims that "the evidence establishes that ethanol and propylene glycol have a function *distinct* from that of the 'osmotic-adjusting agents' in the patents-in-suit," and therefore cannot and "*do not adjust the tonicity of the claimed esmolol solutions*." (HQ's Opp'n at 25 (emphasis in original).) In support of this position, HQ relies upon the fact that the patents-in-suit described the claimed esmolol formulation as "essentially free from propylene glycol and ethanol," and contrast the present invention to prior art that added "propylene glycol and ethanol" in order to increase

[23] There can be no dispute that solubility and tonicity encompass distinct concepts.

solubility. ('540 Patent at 1:44-47, 2:35-37.) This position, however, ignores the reality, exhaustively explained by Baxter (and described above), that common components of a formulation can and often do perform multiple functions. (See Baxter's Reply at 17.) Nor does HQ explain why that fact alone compels the conclusion that HQ's product necessarily uses propylene glycol and ethanol in the same manner.

Second, HQ takes the position that "it is undisputed by those of ordinary skill in the art, including both parties' expert witnesses, that ethanol and propylene glycol do not adjust tonicity of the esmolol formulations at issue in this case." (Id. (emphasis added)) The actual record demonstrates, however, that this issue remains far from undisputed. Indeed, HQ's statement principally relies upon an acknowledgement by Baxter's expert, Dr. Bannister, that ethanol and propylene glycol do not adjust tonicity. (See id.) In so asserting, however, HQ provides an incomplete recitation of Dr. Bannister's actual testimony. Indeed, Dr. Bannister never stated that "ethanol and propylene glycol do not adjust tonicity." (Id.) Rather, he testified that he could not "recall" any scholarly research demonstrating that propylene glycol or ethanol could be used to adjust tonicity, but acknowledged that he "didn't look specifically for that." (Bannister Dep. at 74:7-23.) Even more critically, Dr. Bannister did indeed opine that either compound

could, at least "initially," act in that capacity. (Id. at 74:21-23.)

For all of these reasons, the Court finds that factual disputes preclude the entry of summary judgment in favor of either party. See FED. R. CIV. P. 56(a). The parties' cross-motions for summary judgment will therefore be denied.

V. CONCLUSION

An accompanying Order will be entered.

September 23, 2015
Date

s/ Jerome B. Simandle
JEROME B. SIMANDLE
Chief U.S. District Judge